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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : A61F 2/28, A61L 25/00

A1

(11) International Publication Number: WO 90/04953

(43) International Publication Date: 17 May 1990 (17.05.90)

(21) International Application Number: PCT/SE89/00648

(22) International Filing Date: 10 November 1989 (10.11.89)

(30) Priority data:
8804078-7 11 November 1988 (11.11.88) SE

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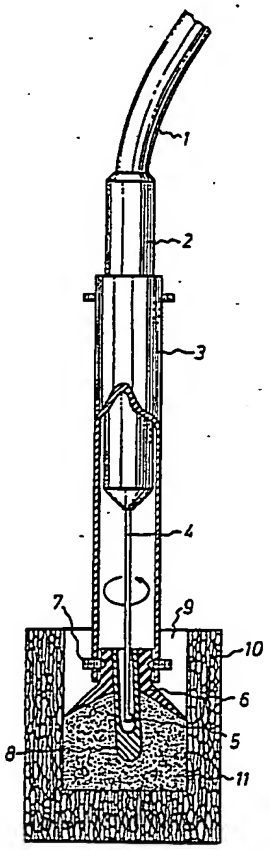
(81) Designated States: AT, AU, BB, BE (European patent), BF (OAPI patent), BG, BJ (OAPI patent), BR, CF (OAPI patent), CG (OAPI patent), CH, CM (OAPI patent), DE, DK, FI, FR (European patent), GA (OAPI patent), GB, HU, IT (European patent), JP, KP, KR, LK, LU, MC, MG, ML (OAPI patent), MR (OAPI patent), MW, NL, NO, RO, SD, SE, SN (OAPI patent), SU, TD (OAPI patent), TG (OAPI patent), US.

Published
With international search report.
In English translation (filed in Swedish).

(54) Title: METHOD AND APPARATUS FOR WORKING BONE CEMENT FOR FIXING A PROSTHESIS IN A BONE

(57) Abstract

In a method for working bone cement (11) placed in a cavity (9) of a bone (10), for instance in the medullary canal of the femur, for fixing a prosthesis in the cavity, the bone cement (11) placed in the cavity (9) is vibrated mechanically. A device for carrying out this method has a vibrating means (8) which is adapted to vibrate the bone cement (11) placed in the cavity (9).



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METHOD AND APPARATUS FOR WORKING BONE CEMENT FOR FIXING A PROSTHESIS IN A BONE

The present invention relates to a method and an apparatus for working bone cement placed in a cavity of a bone, for instance in the medullary canal of the femur, for fixing a prosthesis in the cavity.

In surgical orthopedics in connection with certain joint diseases, such as arthrosis of the hip joint, the natural joint is replaced by a prosthesis of metal or plastic. The prosthesis is fixed in a cavity of the bone, for instance in the medullary canal of the femur, by means of bone cement. Bone cement is prepared by mixing two or more components with each other to form a soft curing mass. The soft mass is placed in the cavity for receiving the prosthesis and, after curing, fixing it in the cavity. The bone cement currently used is of the polymethyl methacrylate type (PMMA) which is prepared by mixing a powder of polymers with a liquid of monomers. The resulting mixture is caused to cure by polymerisation.

To achieve efficient and durable immobilisation of the prosthesis, it is necessary that the soft mass of bone cement upon application penetrates properly and uniformly distributed into the spongy bone and that this takes place with a minimum of injury to bone tissue and blood vessels, and that the cured or polymerised bone cement has a homogeneous structure. If these requirements are not fulfilled, there is an increased risk of the prosthesis coming loose. Today, reoperation after a prosthesis has loosened other than by infections, must be carried out in about 10% of the cases.

When preparing bone cement, it is difficult to avoid that air is admixed into the mass when mixing the different components with each other. The presence of air bubbles in the cured or polymerised bone cement reduces its strength. US Patent Specifications 4,721,390 and 4,758,096 disclose a mixing technique in which the ad-

mixture of air into the bone cement is reduced by mixing the components under vacuum. According to US Patent Specification 4,373,217, the number of air bubbles in polymerised bone cement is reduced by subjecting the mixture to high pressure during a special phase of the polymerisation.

The penetration of the bone cement into the spongy bone depends on how carefully the cavity, for instance a medullary canal, has been cleaned with respect to devitalised tissue. The degree of penetration also depends on the viscosity of the cement and the pressure of application. The lower the viscosity of the cement is and the higher the pressure of application is, the more easily does the penetration take place. With decreasing viscosity and increasing pressure, the PMMA mass however emits a larger amount of highly volatile monomers which have been found to be cytotoxic, that is have an injurious effect on vital cells, and may therefore cause tissue injuries. The monomers may then interfere locally with the flow of blood and also give rise to intravascular hemolysis and inflammatory reactions leading to ischemia, necrosis and resorption of bone substance. However, monomers have been found to produce not only localised injuries but also system injuries, for instance by affecting the heart and by causing fat embolism in the lungs.

Tissue injuries may also arise in other ways. To provide room for a prosthesis, for instance in the femur, the major portion of the bone marrow is removed, which causes injuries to blood vessels and, hence, adversely affects the flow of blood with a consequent risk of ischemia and tissue death. Polymerisation of the PMMA cement takes place with emission of heat, the local temperature increase being proportional to the amount of cement used. Excessive temperature may in itself cause tissue injuries and also, the emission of injurious monomers increases with increasing temperature.

The object of the present invention is to provide a method making it possible to bring about efficient and durable immobilisation of a prosthesis in a cavity by means of bone cement, while overcoming as far as possible the above-mentioned drawbacks by ensuring a thorough and uniformly distributed penetration of bone cement into the spongy bone with a minimum of injuries to bone tissue and blood vessels and a minimum of air bubbles in the bone cement.

According to the invention, this object is achieved by a method for working bone cement placed in a cavity of a bone, for instance in the medullary canal of the femur, for fixing a prosthesis in the cavity, which method is characterised in that the bone cement placed in the cavity is vibrated mechanically.

By vibrating the mass of bone cement, some of the air bubbles resulting from the mixing of the components are eliminated while others are disintegrated into smaller bubbles which, to a lesser extent than the larger air bubbles, form fracture areas in the bone cement. The vibrations increase the moldability and flowability of the mass of bone cement such that it can penetrate into the spongy bone more easily and in a more uniformly distributed manner. Since the penetration of the cement is facilitated, no major pressure need be applied to the cement. By the increased moldability of the mass of bone cement, the curing or polymerisation process can proceed for a slightly longer time than was previously possible, before the mass is applied in the cavity, which makes the PMMA cement emit a reduced amount of injurious monomers in the cavity. As the polymerisation of the PMMA cement is allowed to proceed for a longer time outside the cavity, a substantial amount of the heat generated during the polymerisation is already emitted before the cement comes into contact with the tissues in the cavity.

The bone cement placed in the cavity can be subjected to a slight pressure while being vibrated.

Another object of the present invention is to provide a device for carrying out this method.

According to the invention, this object is achieved by means of a device for working bone cement placed in a cavity of a bone, for instance in the medullary canal of the femur, for fixing a prosthesis in the cavity, which device is characterised by vibrating means adapted to vibrate the bone cement placed in the cavity.

The vibrating means suitably is adapted to execute a rotary movement.

In a preferred embodiment, the device has pressure loading means having a cross-sectional shape corresponding to that of the cavity, and adapted to be introduced in the cavity to be pressed against the bone cement placed therein.

The invention will now be described in more detail with reference to the accompanying drawing which is a part-sectional schematic view of a test device carrying out a test.

The device used in the test and schematically illustrated in the drawing has a flexible shaft 1 which is connected at one end to a motor (not shown) having a speed of rotation of 16,000 rpm, and which is connected at the other end to a chuck 2 normally used in a dentist's drilling equipment. A metal tube 3 is arranged around the chuck 2. A steel pin 4 having a diameter of about 2.5 mm is inserted in the chuck 2 and axially extends a certain distance outside the metal tube 3. The steel pin 4 has a radial projection 5 at its free end. A rubber seal 6 having a central portion and an annular skirt portion is fixed with its central portion to the free end of the metal tube 3 by locking screws 7. The rubber seal 6 has a central through bore in which a metal sleeve 8, closed at its free end, is mounted.

The steel pin 4 extends into the metal sleeve 8 with its radial projection 5 engaging the inner side of the metal sleeve 8 and slightly inclining the metal sleeve. In the drawing, the steel pin 4 is shown in a position of rotation where the radial projection 5 is directed to the right, thus inclining the metal sleeve 8 to the right. When the steel pin 4 is rotating, the metal sleeve 8 executes a movement of rotation, substantially describing a cone.

In the drawing, the device is shown when introduced in a cavity 9 of a bone 10 which in the contemplated experiment is a necrobone from cattle. In the bone 10, consisting of the distal part of the femur cut horizontally just above the condyles, a vertical hole having a depth of about 4 cm and a diameter of about 34 mm has been drilled. The interspongy fat has been removed by heating in water. In the hole, forming the cavity 9, a PMMA bone cement mass 11 was placed after the different components had been mixed. The test device was thereafter introduced in the cavity 9 by descending the metal sleeve 8 into the mass of bone cement 11 and lightly applying to the mass of bone cement 11 the rubber seal skirt portion which as appears from the drawing has substantially the same diameter as the cavity 9. The axial pressure was about 0.2 kp/cm^2. The steel pin 4 and, thus, the metal sleeve 8 were rotated for 30 s, thereby vibrating the mass of bone cement 11, whereupon the device was removed.

After completed polymerisation, the bone 10 was examined, and it clearly appeared that the penetration of the mass of bone cement into the spongy bone was deeper and considerably more uniformly distributed than was the case when the same experiment was conducted without vibrating the mass of bone cement.

CLAIMS

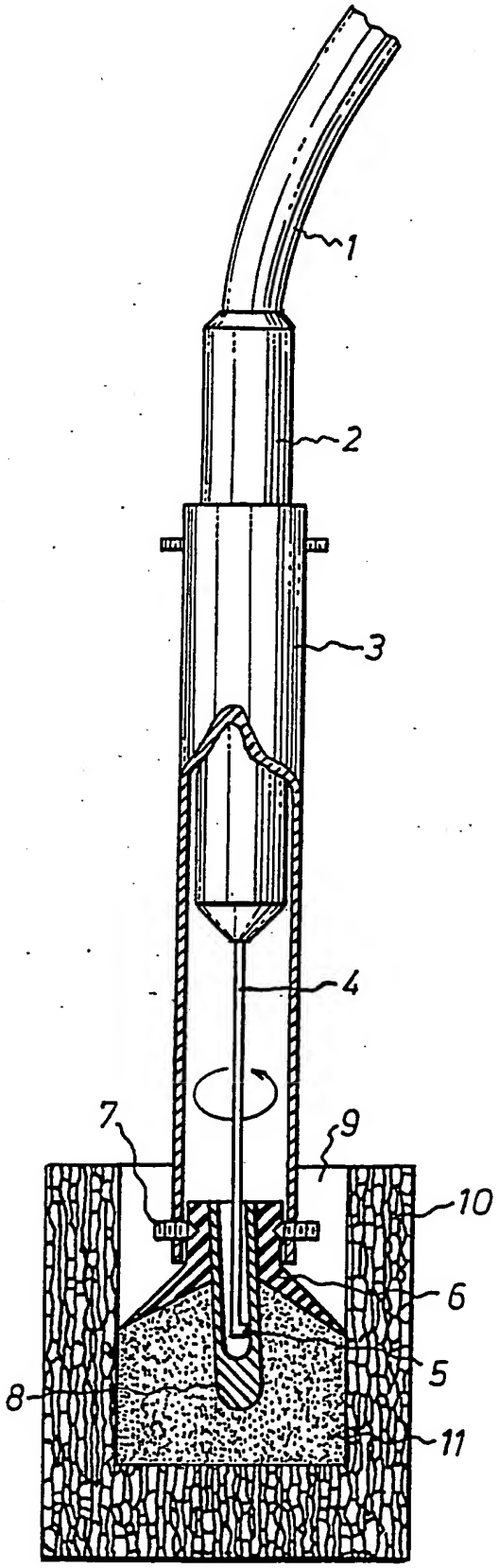
1. A method for working bone cement (11) placed in a cavity (9) of a bone (10), for instance in the medullary canal of the femur, for fixing a prosthesis in said cavity, c h a r a c t e r i s e d in that the bone cement (11) placed in said cavity (9) is vibrated mechanically.

2. Method as claimed in claim 1, c h a r a c t e r - i s e d in that the bone cement (11) placed in said cavity (9) is subjected to a slight pressure while being vibrated.

3. A device for working bone cement (11) placed in a cavity (9) of a bone (11), for instance in the medullary canal of the femur, for fixing a prosthesis in said cavity, c h a r a c t e r i s e d by vibrating means (8) adapted to vibrate the bone cement (11) placed in said cavity (9).

4. Device as claimed in claim 3, c h a r a c t e r - i s e d in that the vibrating means (8) is adapted to execute a rotary movement.

5. Device as claimed in claim 3 or 4, c h a r a c - t e r i s e d by pressure loading means (6) having a cross-sectional shape corresponding to that of the cavity (9), and adapted to be introduced in the cavity to be pressed against the bone cement (11) placed therein.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INTERNATIONAL SEARCH REPORT

International Application No PCT/SE 89/00648

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC5: A 61 F 2/28, A 61 L 25/00

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
IPC5	A 61 F; A 61 L

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

SE,DK,FI,NO classes as above

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category [10]	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
A	SE, A, 8701313-2 (AB IDEA) 1 October 1988, see the whole document --	1-3
A	EP, A2, 0093560 (HOWMEDICA INC.) 9 November 1983, see the whole document --	1,3,5
A	GB, A, 2104390 (UNIVERSITY OF EXETER) 9 March 1983, see the whole document --	1-3,5
A	US, A, 4787751 (BAKELS) 29 November 1988, see the whole document --	1

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* Special categories of cited documents: [10]

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IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
23rd January 1990	1990 -01- 26
International Searching Authority	**Signature of Authorized Officer**
SWEDISH PATENT OFFICE	Leif Karnsäter

ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO. PCT/SE 89/00648

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
SE-A- 8701313-2	01/10/88	NONE	
EP-A2- 0093560	09/11/83	JP-A- 58200755	22/11/83
		US-A- 4462394	31/07/84
		CA-A- 1191759	13/08/85
GB-A- 2104390	09/03/83	EP-A-B- 0073604	09/03/83
US-A- 4787751	29/11/88	NONE	